REMARKS

Claims 1-16 were present in the application when filed. In response to a restriction requirement, Applicants elected the invention of Group 4 (claim 6) and presented new claim 17. Claims 1-17 were pending with claims 1-5 and 7-17 withdrawn from consideration. Claims 1-5 and 7-17 are canceled above. Claim 6, therefore, remains pending in the application.

Rejection under 35 U.S.C. §112, second paragraph

Claim 6 is rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action characterizes the SP-17 designation as a laboratory designation the use of which renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct antigens. The designation SP-17 for the particular antigen encompassed by the present invention is known to those of skill in the art as evidenced by details of the cloning and sequencing reported in Lea et al. "Cloning and sequencing of cDNAs encoding the human sperm protein SP17" (reference CD of Applicants' IDS) Furthermore, the amino acid sequence for the molecule is recorded as accession no. Q15506 in the NCBI protein database. A copy of the NCBI entry for human SP-17 is submitted herewith for the Examiner's convenience.

Rejection under 35 U.S.C. §102

Claim 6 is rejected under 35 U.S.C. §102(a) as being anticipated by Chiriva-Internati et al. (Blood, 2000, 96:272b abstract only). The Office Action alleges that Chiriva-Internati et al. teach an isolated cytotoxic T cell that specifically recognizes Sp-17. This is incorrect. Chiriva-Internati et al. reports on the detection of mRNA transcripts for the spermatozoa protein, SP-17, in tumor cells from multiple myeloma patients. The cited reference does not teach cytotoxic T cells and therefore does not anticipate the claimed invention.

Claim 6 is further rejected under 35 U.S.C. §102(b) as being anticipated by Laurence (U.S. Patent No. 4,665,032). The Office Action states that the '032 patent specifically teaches PBMC isolated from human patients, a subset of which will be cytotoxic T cells that bind to SP17. Applicant respectfully disagrees.

As discussed above, claim 6 recites an isolated cytotoxic T cell which specifically recognizes SP-17. Cytotoxic T cells are a distinct subset of T cells (CD8) that must be "primed," that is, exposed to target antigen, to kill the cells bearing the target antigen. The SP-17 specific cytotoxic T cells of the present invention are generated by stimulation of peripheral blood mononuclear cells (PBMC) with SP-17, followed by isolation of SP-17-specific cells.

In contrast, Laurence teaches a human T cell hybridoma that secretes a soluble suppressor factor (SSF) capable of inhibiting T cell-dependent immune responses. The T cell hybridoma taught by Laurence is the product of a fusion of an immortal human T cell line with a CD4 T cell from a patient with ARC or AIDS.

In generating the T cell hybridoma of Laurence, peripheral blood mononuclear cells (PBMC) are obtained from a male patient with ARC or AIDS. Since normal men who undergo vasectomy represent the only cohort likely to exhibit SP-17 immunoreactivity, it is highly improbable that there would be a significant number of SP-17 specific cytotoxic T cells in cell preparations from ARC or AIDS patients who are more likely than not homosexual men (see col. 5, Example 1 A.)

Thus, neither Chiriva-Internati et al. nor Laurence teach or fairly suggest an isolated cytotoxic T cell which specifically recognizes SP-17 and therefore the cited references cannot anticipate the claimed invention. Withdrawal of the rejection is respectfully requested.

The Office Action also states that the specification does not define the term "isolated," and therefore, for examination purposes, the term "isolated" is understood to mean T-cells isolated from the blood stream. Applicant believes that one of skill in the art would recognize that the term "isolated" used in the context of an immune cell indicates a cell preparation in which the specific cell type desired is isolated not only from peripheral blood but also from other immune cells in the peripheral blood mononuclear cell preparation. Thus, in the instant case, the term "isolated cytotoxic T cell" represents a preparation of T cells in which B cells, monocytes and the like are removed. Procedures for isolating subpopulations of immune cells, for example T cells and further isolation of T cell subsets from those populations, for example, $CD8^+$ T cells, are well know to those of skill in the art.

For the foregoing reasons, claim 6 is believed in condition for allowance and such action is respectfully requested.

Should the Examiner require clarification of any of the above, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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